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October 20, 2005

Elias A. Zerhouni, M.D. Director National Institutes of Health 9000 Rockville Pike Bethesda, Maryland 20892

Dear Dr. Zerhouni:

This letter is in response to your recent letter, dated October 7, 2005, responding to my inquiry of May 18 raising serious concerns about the ethical and conflicts-of-interest issues surrounding Dr. James Battey's recusal and reinstatement as Chair of the NIH Stem Cell Task Force, while also seeking employment as the President of the California Institute for Regenerative Medicine.

You state in your letter that once Dr. Battey informed NIH officials he was a candidate to head the California Institute for Regenerative Medicine, he was advised "that he would be required to step down [as Chair of the Task Force] to comply with the ethics requirements," and that on March 18, you announced his leave of absence from his position as Chair.

However, during the time Battey was *no longer* Chair of the NIH Stem Cell Task Force, he nonetheless gave several presentations on stem cell research, including one at a California biotech council investors conference. You wrote that Dr. Battey "gave these presentations as an NIH employee," and that they were "part of Dr. Battey's official duties."

I find the justifications for Dr. Battey's continued formal speaking engagements on the subject of stem cell research during this period of "recusal" insupportable.

The presumption is that Dr. Battey, when he is not the Chair of the Stem Cell Task Force, carries only the official NIH title of Director for the National Institute on Deafness and Other Communication Disorders. That being the case, how does giving speeches on the "politics" or the "business" of stem cell research fall within the "official

HENRY A. WAXMAN, CALIFORNIA,

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duties" of the Director for the Institute on Deafness and Other Communication Disorders?¹

If Dr. Battey's employment negotiations with the California Institute for Regenerative Medicine posed a conflict of interest requiring him to step down as Chair of the NIH Stem Cell Task Force to comply with ethics requirements, wouldn't this require him to forgo speaking opportunities that spring from his role as Chair? Wouldn't it have been more appropriate for the NIH to send one of the acting co-Chairs of the Stem Cell Task Force?

It is rather difficult to see any meaningful difference between Dr. Battey's official activities as Chair of the Stem Cell Task Force, and those when he was supposedly not acting as Chair. For example, Dr. Battey's Powerpoint presentation for speeches on stem cell research was *unchanged* from what he presented as Chair of the Stem Cell Task Force to what he presented when he was not Chair.²

Moreover, how has NIH affirmed that Dr. Battey did not stray from the parameters you describe in your letter for his "official" presentations, strictly limiting Dr. Battey's discussions "to previously released information about Federal stem cell policies without discussing any NIH plans or initiatives related to future stem cell research?"

I am confounded by Dr. Battey's appearance – during the time he was *not* Chair because of the conflict of interest arising from his candidacy to head the California Institute for Regenerative Medicine – at a California biomedical *investor* conference. The vague listing that was provided to the Subcommittee of Dr. Battey's appearances (to which Dr. Battey himself contributed and corrected³) omits this troubling detail.⁴

¹ Dr. Battey's speeches during the period when he was *not* Chair of the Stem Cell Task Force include the following events: "The Politics of Stem Cell Research," and "The Business of Stem Cell Research." One press release dated April 7 touting the Business of Stem Cell Research Conference listed as part of its roster of speakers "Dr. James Battey of the National Institute [sic] of Health (NIH) Stem Cell Task Force," to discuss "the current state of the science *and future outlook of stem cell research*" (emphasis added). (Press release vailable at http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www/story/04-07-2005/0003338634&EDATE="http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www/story/04-07-2005/0003338634&EDATE="http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www/story/04-07-2005/0003338634&EDATE="http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www/story/04-07-2005/0003338634&EDATE="http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www/story/04-07-2005/000338634&EDATE="http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www.prnewswire.com

² In response to the Subcommittee's initial inquiry (May 5, 2005) to HHS requesting a list of appearances and transcripts for Dr. Battey's speeches since March 1, 2005, the Subcommittee received a listing of only two appearances. Although no transcript was provided, a Powerpoint presentation was attached, with the note that Dr. Battey used the slides for presentations on stem cell research on March 4-5 (when he was still Chair of the Stem Cell Task Force) and on March 18 (when Dr. Battey was *not* Chair of the Stem Cell Task Force). Moreover, as we pointed out in our May 18 correspondence on this matter, the Subcommittee was told that "these were the only two presentations [Dr. Battey] made on Stem Cell Research during the time requested." However, Subcommittee staff determined the listing to be incomplete, and after another inquiry (May 9) for Dr. Battey's appearances, the Subcommittee was provided with a listing of twelve appearances. (Flambert, Gemma, email response to "Battey inquiry," May 9, 2005, and "House Government Reform Request," on May 12, 2005. On file with the Subcommittee.)

³ According to Zerhouni's October 7 letter to the Subcommittee.

⁴ The listing for "Public Appearances and speeches on Stem Cell Research, Dr James Battey" provided to the Subcommittee notes an appearance on March 22 for "Workshop on Stem Cell Research, Where is the Beef?" for the "Southern California of Biomedical Council [sic], Los Angeles, CA." The listing failed to

The panel on which he spoke is listed in the program as "Opportunities in Stem Cell Research," "organized in recognition of the importance of the California Stem Cell Research Initiative⁵ and to stimulate thinking about its likely impact on healthcare delivery and job creation." This topic does not appear to meet the parameters you described in your letter. Is this the topic on which Dr. Battey spoke?

Considering the ethical and conflict of interest issues raised by Battey's candidacy to head the California Institute for Regenerative Medicine, it is simply absurd:

- that Dr. Battey presented at an investor's conference,
- for a California Biomedical Council
- promotionally noted as speaking on the material matter of stem cell research and its relationship to the California Stem Cell Research Initiative,
- as an official of the National Institutes of Health,
- during the time when he was supposedly conflicted out of his role as Chair of the NIH Stem Cell Task Force
- because he was a candidate for the position of President of the California Institute for Regenerative Medicine.

Dr. Zerhouni, I am deeply troubled by the possibility that NIH has not taken seriously the ethical and conflict of interest problems posed by Dr. Battey's activities. I question the level of vigilance against blatant conflicts of interest in light of the following:

If Dr. Battey was strictly limited to presenting "previously released information about the Government's stem cell policy," and not to "discuss any new directions that the NIH may be taking with respect to stem cell research," what was his involvement with the National Institute of General Medical Sciences (NIGMS) workshop, "Human Embryonic Stem Cell Research: Recent Progress and Future Directions of NIGMS Grantees?"

The purpose of this meeting, for which Dr. Battey is a listed participant⁸ was "to provide an opportunity for NIGMA grantees conducting human embryonic stem cell (HESC) research to report on their recent progress, to exchange information, and to

disclose the fact that the meeting was actually an annual investors conference. See http://www.socalbio.org/investor conference.htm (last visited October 19, 2005).

⁵ The Initiative provided for the establishment of the California Institute for Regenerative Medicine.

⁶ SoCalBio Investor Conference brochure, available at

http://www.socalbio.org/socalbio2005/2005 brochure1.pdf (last visited October 13, 2005).

⁷ Stem Cell Initiatives, National Institute of General Medical Sciences, April 17-19 workshop. A summary and list of participants posted at http://www.nigms.nih.gov/funding/stemcell_human_embryo_meeting.html (last visited October 14, 2005). Sometime on the afternoon of October 14, when the Subcommittee was investigating this matter, the NIGMS webpage listing information about the Stem Cell funding workshop became inactive. The material printed from this webpage prior to its removal is on file with the Subcommittee.

⁸ Id.

identify problems, challenges and opportunities associated with this emerging area of research."

Among the sixty-eight participants in this important stem cell research grantee meeting, Dr. Battey is the only Institute Director listed; nine more participants are affiliated with NIH. Of the remaining fifty-eight researcher grantees, ten are California-based. All of the California researchers' affiliated institutions would have been candidates for multi-million dollar grants from the California Institute for Regenerative Medicine. (The California Institute for Regenerative Medicine has since awarded \$15.9 million in grants to California institutions represented at this workshop. ¹⁰)

To the extent that Dr. Battey could have participated in *any* workshop addressing "opportunities" for stem cell research grantees while a candidate to head the California Institute for Regenerative Medicine is quite alarming. That a large percentage of the participating researchers were would-be grantees for the California Institute for Regenerative Medicine shocks the conscience.

Finally, assuming Dr. Battey had at least some contact with representatives from the California Institute for Regenerative Medicine prior to mailing his application seeking the prominent position of President with that group (on March 12, according to your letter), wouldn't this necessarily trigger his recusal as Chair of the Stem Cell Task Force (a minimal gesture), earlier than March 18?

Dr. Zerhouni, based on the activities described above, Dr. Battey's "recusal" as Chair of the Stem Cell Task Force appears to have been utterly meaningless. There does not appear to be any substantive measures against the conflict of interest between Battey's role as a government official and as an applicant to head the California Institute for Regenerative Medicine.

As you may know, I have requested the Inspector General to investigate this matter regarding Dr. Battey's activities. In addition to what appears to be serious ethical and conflict of interest issues, I believe that his activities reveal systemic weaknesses that give rise to opportunities for waste, fraud and abuse.

I have asked a number of serious questions throughout this letter, which merit a response. I do not want to wait almost five months for answers, as with my first letter to you on this matter. Rather, I expect the courtesy of a full response not later than 5:00pm on Friday, December 2, 2005. This deadline is several weeks from now, and should be adequate time to address these questions posed by the Chairman of your oversight committee.

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[.] 14

¹⁰ California Institute for Regenerative Medicine Press Release, September 9, 2005. Available at http://www.cirm.ca.gov/pressreleases/2005/09/09-09-05_ii.asp (last visited October 19, 2005).

In addition to answering the questions posed in this correspondence, please also provide the following:

- All documents relating to Dr. Battey's removal and reinstatement as Chair of the NIH Stem Cell Task Force, including but not limited to memoranda on March 18, and May 19 to Institute Directors about Dr. Battey's position and duties (see attachment for definition of "documents" and "relating to").
- All documents related to Dr. Battey's affirmation that he adhered to the parameters set forth by ethics officials regarding the scope of his presentations on stem cell research (see attachment for definition of "documents" and "relating to").
- All documents related to NIH's official determination that Dr. Battey adhered to the parameters set forth by ethics officials regarding the scope of his presentations on stem cell research (see attachment for definition of "documents" and "relating to").
- Copies of presentations, transcripts, audio or video recordings for Dr. Battey's presentations on the subject of stem cell research during the period of his "recusal."
- All documents relating to Dr. Battey's notification (1) that he was seeking employment with the California Institute for Regenerative Medicine; and (2) that he was no longer a candidate for any position at the California Institute for Regenerative Medicine (see attachment for definition of "documents" and "relating to").
- All meeting notes, participant lists, and audio recordings, related to the NIGMS Stem Cell Initiatives Research Funding workshop on April 17-19 of this year.

Sincerely,

Chairman

Subcommittee on Criminal Justice, Drug Policy and Human Resources

Government Reform Committee

Mar Jande

Attachment: Definitions

Enclosures: Prior correspondence

CC: Hon. Michael Leavitt, Secretary,

Department of Health and Human Services

Claude Allen, Assistant to the President for Domestic Policy

Daniel R. Levinson, Inspector General,

Department of Health and Human Services

ATTACHMENT

- 1. The term "documents" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements. drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intraoffice and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
- 2. The terms "related to" or "relating to" means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health Bethesda, Maryland 20892

OCT 7 2005

The Honorable Mark Souder
Chairman, Subcommittee on Criminal Justice,
Drug Policy and Human Resources
Committee on Government Reform
House of Representatives
1227 Longworth House Office Building
Washington, D.C. 20515

Dear Mr. Souder:

I am writing to respond to your concerns regarding Dr. James Battey, Director of the National Institute on Deafness and Other Communication Disorders. As you have noted, Dr. Battey was a candidate for the position of President of the California Institute for Regenerative Medicine during the spring of this year. As you know, seeking prospective employment, as the term is defined for purposes of the Government-wide Standards of Ethical Conduct for Employees of the Executive Branch, triggers certain recusal obligations depending upon the precise facts of the case. Where an employee is seeking employment, but is not yet negotiating for employment, the recusal obligation is regulatory. See, 5 C.F.R. § 2635.604(a). Where, however, such discussions or communications are mutually conducted with a view toward reaching an agreement regarding possible future employment, such employment "negotiations" trigger a disqualification obligation under Section 208 of Title 18 of the United States Code, 18 U.S.C. § 208, because the financial interests of the prospective employer are imputed to the employee. In either case, the employee is prohibited from participating personally and substantially in an official capacity in any particular matter in which, to his knowledge, he will have a direct and predictable effect on the interests of the prospective employer.

The United States Office of Government Ethics (OGE) has opined that a speech given by an employee in his official capacity may be a particular matter under § 208. A speech that solely presents previously released factual information would not, however, likely have a "direct and predictable effect," as the term is defined at 5 C.F.R. § 2640.103(a)(3), on the interests of any entity. An effect is "direct," for these purposes, where there is a close causal link between the decision or action on the matter and any expected effect on the financial interest, and "predictable" where an effect on the financial interest is a real possibility not merely a speculative one. *Id.* Moreover, if the matter at issue in this case is the NIH implementation of the Federal stem cell research program, then presenting previously released factual information on the matter would not constitute "personal and substantial participation," as defined for these purposes at 5 CFR § 2640.103(a)(2), in the matter. Such participation generally occurs when an employee participates through decision, recommendation, or other action. *Id.* While the term is not limited to action or decision that is determinative of the matter, it does require more than perfunctory or administrative involvement, and must be of significance to the matter. *Id.*

Page 2 - The Honorable Mark Souder

I understand that on March 12, 2005, Dr. Battey applied for the position of President of the California Institute for Regenerative Medicine. On March 15, 2005, the first business day after mailing the application, Dr. Battey informed NIH officials that he was a candidate for the position. He was immediately advised that continuing as the Chair of the NIH Stem Cell Task Force during this period would likely result in a conflict of interest and that he would be required to step down to comply with the ethics requirements. By memorandum dated March 18, I then announced to the NIH Institute Directors that Dr. Battey was taking a leave of absence from his position as Chair of the Task Force.

In relation to speaking engagements, Dr. Battey was advised specifically of how delivering speeches in his official capacity could violate the recusal obligation. Ethics officials advised, however, that it would be possible to make a presentation without violating the recusal obligation(s) provided the content was limited strictly to previously released information about the Government's stem cell policy and did not discuss new directions that the NIH may be taking with respect to stem cell research. The parameters included limiting his discussions to previously released information about Federal stem cell policies without discussing any NIH plans or initiatives related to future stem cell research. Once advised, Dr. Battey, like all employees in similar circumstances, was expected to comply with the guidance. Dr. Battey has affirmed that he adhered to these parameters. Dr. Battey gave these presentations as an NIH employee and not in his personal capacity as an outside activity. I am informed that he received no compensation for these duties other than his NIH salary, and because these speeches were part of Dr. Battey's official duties and not outside activities, Dr. Battey was not expected to report them as outside activities.

I understand that in early May, Dr. Battey notified the California Institute for Regenerative Medicine that he was no longer interested in pursuing prospective employment. On May 19, Dr. Zerhouni informed the NIH Institute Directors that Dr. Battey had resumed his duties as Chair of the NIH Stem Cell Task Force.

Please let me know if you have further questions.

Sincerely,

Elias A. Zerhouni, M.D.

Director

Enclosure

¹ Dr. Battey has indicated that the initial list provided to the Subcommittee via email on May 9, and attached to the May 18 letter, contained a minor error regarding the date of one of his public appearances. In addition, one of the appearances listed (March 15, Tribute Reception) did not involve a presentation. Dr. Battey merely attended a reception, referred to under the ethics regulations as a "widely attended gathering." Dr. Battey did not give a presentation at this event, and, consistent with applicable regulations, he attended in his personal capacity. A corrected list of presentations is enclosed.

CORRECTED LIST OF PRESENTATIONS

March 4-5	Stem Cell Conference	Smith College, Northampton, MA
March 9	Opening Address: "The Business of Stem Cell Research"	American Enterprise Institute, 1150 17 th Street, N.W., Washington, D.C.
March 18	The Politics of Stem Cell Research; The Stem Cell Controversy	The National Institute of Science, Beta Kappa Chi Honor Society, The Omni Hotel, Richmond, VA
March 22	"Workshop on Stem Cell Research, Where is the Beef?"	Southern California of Biomedical Council, Los Angeles, CA.
April 6	Senate Appropriations Hearing	Senate Office Building, Washington, D.C.
April 11	NIH and Stem Cell Research	University of Utah, Genetic Science Learning Center, UT
April 18	Stem Cell Workshop	NIH, NIGMS, Pooks Hill Marriott, Bethesda, MD.
April 25	Business of Stem Cell Research Conference	Bethesda North Marriott Hotel and Conference Center, Bethesda, MD.
April 26	Georgetown Chapter of Sigma XI	Georgetown University, School of Medicine, Washington, DC
May 6	Research Dean's Meeting	AAMC, Ritz Carlton, Pentagon City, VA.
May 10	Presentation on Stem Cell Research	National Multiple Sclerosis Society, Mayflower Hotel, Washington, D.C.

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May 18, 2005

The Honorable Michael Leavitt Secretary Department of Health and Human Services 200 Independence Avenue, S.W. Washington, DC 20201

Dear Mr. Secretary:

We are writing this letter to bring your attention to some matters of concern regarding Dr. James Battey, who allegedly resigned as Chairman of the NIH Stem Cell Task Force, but has since "unresigned" (if that is the word) his Chairmanship of this important group.

On May 6, Subcommittee staff requested from NIH a list and transcripts of Dr. Battey's speeches or public appearances since March 1 of this year, where the issue of stem cell research was a topic at those events. We received a response on May 9, listing **two** presentations (Smith College on March 4-5; Richmond, VA on March 18). We were told that "[t]hese were the only two presentations [Dr. Battey] made on Stem Cell Research during the time requested."

However, a brief search on the internet revealed at least one additional public appearance where the subject matter was stem cell research, so again on May 9 Subcommittee staff renewed the request for a list of "all public appearances since March 1 of this year" where Dr. Battey spoke on stem cell matters, and transcripts where available.

On May 11, we received a response listing **twelve** presentations.² It was in this response that we were also informed that Dr. Battey had "resumed" Chairmanship of the Stem Cell Task Force, a position from which he had resigned on March 18 citing the new NIH conflict of interest rules as prompting his resignation.³ We were also told that transcripts were not available, except for Dr. Battey's appearance on April 6, 2005 before the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and related Agencies.

HENRY A. WAXMAN, CALIFORNIA, RANKING MINORITY MEMBER

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DISTRICT OF COLLIMBIA

BERNARD SANDERS, VERMONT, INDEPENDENT

¹ Flambert, Gemma, email response to "Battey inquiry," May 9, 2005.

² The chart provided to us listing these appearances is attached to this letter.

³ The new conflict of interest rules were widely reported in the media, and the matter was a significant topic of your April 6 testimony before the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and related Agencies.

Important to this matter is the fact that Dr. Battey was a candidate for the position of President of the California Stem Cell Institute, which was widely reported and even referenced during his Senate testimony on April 6, 2005.

Between the period where Dr. Battey formally resigned his Chairmanship of the Stem Cell Task Force (March 18) and when he "resumed" Chairmanship (May 6)⁴, he made at least six public speeches or presentations on the subject of stem cell research, and numerous statements to the media on matters related to stem cell research.

The timing and circumstances of Dr. Battey's actions in the last few months raises serious conflict of interest issues. Dr. Battey continued to make formal appearances on the matter of stem cell research as an employee of the NIH, while also publicly a candidate for the California Stem Cell Institute President. We have concerns that "resigning" the Chairmanship and later "un-resigning," while making public speeches and statements related to the central issues of the Stem Cell Task Force appears improper, and perhaps violated the NIH's own ethics guidelines.

First, it is unclear in what capacity Dr. Battey was making public statements and formal appearances dealing with stem cell research: Was it as a representative of NIH, and if so, as head of the Stem Cell Task Force? As the former head of the Stem Cell Task Force? As a job candidate for the California Stem Cell Institute? Obviously, the distinctions are important.

According to the ethics guidelines posted on NIH's website, "an employee may engage in outside activities that require the use of professional qualifications readily identified with his or her NIH position, provided his/her outside work does not create a real or an apparent conflict of interest or interfere with regularly assigned official Government duties." The NIH also prohibits activities related to an employee's official duties:

- 1. Activities Must Not Be Related to Official Duties: An employee may not receive compensation for outside activities that relate to his/her official duties and responsibilities as an NIH employee. An activity is considered related to current official work if:
 - it is done as part of official duties or the employee was invited to perform the activity primarily because of the employee's official position, or
 - o it deals with any matter to which an employee is presently assigned, or has been assigned during the previous one-year period; or
 - o if it deals with any ongoing or announced policy, program or operation of the NIH.6

The NIH considers "giving formal speeches or presentations on a scientific or professional topic based on the employee's personal expertise" as an outside activity.

⁶ Id.

⁴ According to the material provided to us in the response to our request (Flamberg email on May 11, 2005).

⁵ National Institutes of Health Ethics Program, Outside Activities, available at http://ethics.od.nih.gov/topics/oa520.htm (last visited May 16, 2005).

⁷ Id.

The Subcommittee is interested in whether Dr. Battey's public statements and appearances between the time he "resigned" and the time he "resumed" his chairmanship were "outside activities" for which he was compensated, and for which he must file a report, in accordance with NIH guidelines. If so, wouldn't such activities, clearly related to Dr. Battey's official duties during the last year, be prohibited by NIH ethics rules?

If Dr. Battey was not compensated, nevertheless the fact that he was speaking on these issues while also a candidate for the California Stem Cell Institute raises concerns. The NIH Ethics Program states that "a 'Conflict of Interest' arises when an employee is involved in a particular matter as part of his/her official duties with an outside organization with which he/she also has a financial interest, or one which is imputed to him/her, i.e.,...a person or organization with which the employee is negotiating for prospective or has an arrangement for prospective employment."

What procedures were followed in approving Dr. Battey's high-profile appearances on a matter that is of such national significance, and for which he held a very prominent position?

Although we were informed that Dr. Battey is no longer a candidate for the California job, it is now unclear whether Dr. Battey has actually "rescinded" his resignation from NIH. In response to our last inquiry regarding Dr. Battey's employment status, we were informed that Dr. Battey "is hoping that the issues that he raised when he stated his intent to resign will be resolved so he can remain in his current position."

Who in the department accepted Dr. Battey's resignation as Chairman of the Stem Cell Task Force? Who accepted Dr. Battey's "un-resignation," and restored him to the said chairmanship? To whom is the resignation reported? What effect does the resignation have on an employee's ethical obligations to the NIH and the Department?

Obviously, considering the importance and controversial nature of the stem cell issue, the appearance of integrity is paramount. However, this situation raises some troubling concerns that we hope you will address.

Finally Mr. Secretary, the last time we sent an oversight request to HHS dealing with critical stem cell research issues, we did not receive a response until after a very unreasonable delay, and the response was inadequate. Specifically, on October 8, 2002, Congressman Chris Smith and I requested "a detailed report" providing comprehensive information about the medical applications of adult and embryonic stem cells as well as stem cells from cloned embryos and aborted fetuses.

Our request was followed by numerous phone calls and a series of eight communications in writing over the subsequent 20 months. The response we finally received on June 18, 2004, stated that there were no treatments or ongoing clinical trials utilizing embryonic stem cells or stem cells from cloned embryos or aborted fetuses. The NIH letter also reported the adverse effects resulting from the two known clinical trials using fetal tissue transplantation to treat

⁹ Flambert, Gemma, email response to "House Government Reform Request," May 12, 2005

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⁸ National Institutes of Health Ethics Program, Conflicts of Interest, available at http://ethics.od.nih.gov/Topics/coi.htm (last visited May 16, 2005).

Parkinson's disease. This letter was signed by Dr. James Battey. However, the Subcommittee raised numerous material defects in the Department's response, particularly that the response did not address the plain meaning of the Subcommittee's original oversight request. (A copy of our letter to Secretary Thompson regarding this matter is attached.)

We ask that you address the issues raised in this letter regarding Mr. Battey's activities and his employment status, and look forward to receiving your response on these matters by May 27, 2005.

Thank you for your attention to this matter. If you have any questions, please have a member of your staff contact the clerk of the Subcommittee, Malia Holst, at (202) 225-2577.

Sincerely,

Mark E. Souder

Chairman

Subcommittee on Criminal Justice, Drug

Policy, and Human Resources

Enclosure

Public Appearances and Speeches on Stem Cell Research Dr. James Battey

		The National Institute of
C	ell Controversy	Science, Beta Kappa Chi
		Honor Society, The Omni
		Hotel, Richmond, VA
4-5 St	em Cell Conference	Smith College, Northampton,
		MA
9 O ₁	pening Address: "The Business of Stem Cell	American Enterprise Institute,
Re	esearch"	1150 17 th Street, N.W.,
		Washington, D.C.
15 Tr	ribute Reception	Research!America, Tribute
		Reception, Willard Hotel,
		1401 PA, Ave, N.W.,
		Washington, D.C.
22 "V	Workshop on Stem Cell Research, Where is	Southern California of
the	e Beef?"	Biomedical Council, Los
		Angeles, CA.
Se	enate Appropriations Hearing	Senate Office Building,
		Washington, D.C.
1 NI	IH and Stem Cell Research	University of Utah, Genetic
		Science Learning Center, UT
8 Ste	em Cell Workshop	NIH, NIGMS, Pooks Hill
		Marriott, Bethesda, MD.
5 Bu	usiness of Stem Cell Research Conference	Bethesda North Marriott Hotel
		and Conference Center
5 Ge	eorgetown Chapter of Sigma XI	Georgetown University,
		School of Medicine,
		Washington, DC
Re	esearch Dean's Meeting	AAMC, Ritz Carlton,
		Pentagon City, VA.
Pro	esentation on Stem Cell Research	National Multiple Sclerosis
		Society, Mayflower Hotel,
		Washington, DC
	Ca Ca Ca Ca Ca Ca Ca Ca	Cell Controversy Stem Cell Conference Opening Address: "The Business of Stem Cell Research" Tribute Reception "Workshop on Stem Cell Research, Where is the Beef?" Senate Appropriations Hearing NIH and Stem Cell Research Stem Cell Workshop Business of Stem Cell Research Conference Georgetown Chapter of Sigma XI Research Dean's Meeting